# AUCKLAND WOMEN'S HEALTH COUNCIL

# NEWSLETTER

## AUGUST 2012

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## MEDSAFE'S CLAIMS RE PIP BREAST IMPLANTS

In response to the letter the AWHC wrote to Medsafe, New Zealand Medicines and Medical Devices Safety Authority, about the problems with PIP breast implants in the wake of news that a number of New Zealand women had had them implanted, the Council has received a letter with the astonishing claim that these breast implants pose no more risks than any other brand of silicone gel-filled implant.

The scandal that broke at the end of last year centred on Poly Implant Prosthese (PIP), a leading international manufacturer of silicone breast implants. The French implants were among the cheapest in the world and it was revealed they were filled with an industrial grade silicone. The implants had come under suspicion after doctors reported an abnormal number of rips and leaks in these particular implants.

According to Medsafe the doctors were wrong. "The failure rate (from a rupture or leak) for the PIP breast implants is around 0.4% for every year of implant and this comparable to other similar implants," Stewart Jessamine, Medsafe's group manager, wrote.

Tests by regulators in France, Australia and the UK and a subsequent review of the data by expert committees "has so far found no evidence of harm or toxicity associated with the filler used inside the PIP implants," he explained. "On this basis, the health risks from a PIP implant is no different from that of any other breast implant."

However, the Medsafe website contains the following disclaimer to there being no evidence of harm:
"*This reassurance should be cautioned by the limited level of knowledge at this stage*." (1)

It should be noted that Medsafe is <u>not</u> claiming that the PIP implants are safe. The letter simply points out that the risks are no greater than those for other brands, and that the risks of surgery to remove the implants may be greater than the risk posed by the PIP implants. "Removal of a PIP or any other breast implant is only recommended where a patient's doctor/surgeon believes it necessary due to rupture or other health concern," Stewart Jessamine wrote.

The message from Medsafe is that women must leave it to their doctor to make the decision about whether to have their implants removed, and it is not recommended that they do anything until the implant ruptures or something else happens.

**History repeats itself**

It is of considerable concern that Medsafe is responding to the PIP breast implant issue as though it is a new problem.

Silicone breast implants were first marketed in 1963 by their inventors, the Dow Corning Corporation. It was decades before there were any regulations or testing to ascertain if they were safe. The US Food and Drug Administration (FDA) waited until 1992 to require manufacturers to prove that silicone implants were safe.

In the early 1990s complaints began surfacing about serious illnesses women were experiencing as a result of their implants. The symptoms they

described included numbness of their limbs, joint pains, rashes, chronic fatigue, migraines, loss of appetite, and diminished sex drive.

In January 1992, the FDA asked all surgeons to stop using silicone breast implants while they evaluated research to determine if there was a link between leaking silicone breast implants and diseases such as rheumatoid arthritis, scleroderma (a painful tightening and thickening of the skin) and rare auto-immune diseases. The NZ Department of Health gave NZ surgeons the same advice.

Dow Corning was then faced with a barrage of lawsuits for damages from its silicone breast implants. Women in NZ who had suffered problems as a result of leaking silicone were able to join the lawsuit and bring legal proceedings in the US.

In 1998 410,000 women were awarded a $4.23 billion global settlement against Dow Corning. It took a further four to five years before some NZ women received their share of the settlement as a result of a class action by law firm Slater and Gordon for 2400 women, most of whom were from Australia, and even longer for another 1200 women in NZ who were represented by Michael Okkerse.

While the controversy continued about the link between silicone breast implants and the diseases that women were subsequently diagnosed with, there was never any doubt that breast implants did and still do have side effects.

One of the most serious and common complication is capsular contracture. This occurs when the body forms a thick layer of scar tissue around the implant. The tissue then hardens and contracts as the body attempts to isolate and remove the foreign body.

In 2000 the British Department of Health informed women considering implants that 10% of women suffer from contracture, “causing the implant to deform, become hard and, in some cases, painful.” In a severe contracture the breast is firm, hard, tender, painful, and cold. Distortion is marked. The US Institute of Medicine found that this severe form of capsular contracture affects not 10% of women but 100% of those who have had silicone implants for 25 years. (2)

Other side effects include red, thick, painful scars that can take several years to improve, painful nipples for three to six months following surgery, and the risk of the implant rupturing. All implants interfere with the ability of x-rays to detect the early signs of breast cancer by compressing the remaining breast tissue and impairing the ability to view changes.

Up to a quarter of women will have to have their implants replaced within five years, a rate that would not be regarded as acceptable in other devices.

Given the evidence that breast implants don’t work very well and often cause problems, why is Medsafe and the Ministry of Health not strongly advising women against them.

**References**

1. http://www.health.govt.nz/news-media/news-items/pip-implant-advisory-and-frequently-asked-questions
2. http://ukfeminista.org.uk/wp-content/uploads/2012/07/Cosmetic_surgery_culture_and_choice.pdf

## *THE $3 BILLION FINE*

Last month the British drug company GlaxoSmithKlein (GSK) was fined $US3 billion after admitting to a multi-year criminal scheme to hide unhelpful scientific evidence, manipulate articles in medical journals and lavish gifts on sympathetic doctors. It was the largest settlement to date involving a pharmaceutical company.

The settlement included $US2 billion in civil penalties which resolved claims that GSK had billed government-run healthcare plans too much for many drugs, although the drug company refused to admit any wrongdoing in the civil settlement.

**Bribes, kickbacks and trickery**
During the investigation it was revealed that GSK encouraged sales reps in the US to heavily promote two antidepressant drugs Paxil and Wellbutrin, and the asthma drug Advair to doctors, and lavished hospitality and kickbacks on those who agreed to write extra prescriptions. These included trips to resorts in Bermuda, Jamaica, Hawaii and California where doctors and their families were treated to snorkelling, horse-riding, sailing, deep-sea fishing, balloon rides and spa treatments, and given an "honorarium" of $US750 in cash.

**Paxil**
GSK pleaded guilty to the promotion of Paxil and Wellbutrin for unapproved uses. Paxil was only approved for adults, yet GSK promoted it as being suitable for children and teenagers from 1998 to 2003, despite two scientific studies that showed it was ineffective in treating childhood depression.

Because of the increased risk of suicidal thoughts and suicide attempts when these powerful drugs are prescribed for young people, children and teenagers should only be treated with antidepressants in very exceptional circumstances. Following the heavy duty and highly successful promotion of Paxil for use in teenagers and children, GSK was subsequently hit with jury verdicts and had to settle thousands of cases alleging that Paxil caused suicides, addiction and birth defects in babies who mothers used the drug during pregnancy.

**Wellbutrin**
GSK also pleaded guilty to illegally promoting Wellbutrin for the treatment of adult impotence, obesity and attention deficit disorder.

**Avandia**
In response of another charge GSK pleaded guilty to failing to report to the government for seven years the safety data about a top diabetes drug, Avandia, which was restricted in the US and banned in Europe after it was found in 2007 to sharply increase the risks of heart attacks and congestive heart failure.

Under the terms of the settlement with the Department of Justice, GSK company managers, all the way up to GSK's chief executive, Sir Andrew Witty, will have their pay and bonuses clawed back if there is any further wrongdoing. "For far too long, we have heard that the pharmaceutical industry views these settlements merely as the cost of doing business," said Acting Assistant Attorney General Stuart Delery, head of the civil division of the Department of Justice. The settlement is about not only punishing wrongdoing and

recovering taxpayer dollars, but to ensure GSK's future compliance with the law, he said.

**The whistle-blower law**

The $3 billion dollar fine makes this year a record for money recovered by the US federal government under its so-called whistle-blower law. In May, Abbot Laboratories settled for $1.6 billion over its marketing of the anti-seizure drug Depakote. An agreement with Johnson & Johnson that could result in a fine of as much as $2 billion is said to be imminent over its off-label promotion of an anti-psychotic drug, Risperdal and two other drugs.

The case against Glaxo was originally brought in January 2003 by two whistle-blowers, former Glaxo sales representatives Greg Thorpe and Clair Hamrick. The two raised their concerns with the drug company management who were slow to begin an investigation and did nothing to stop the illegal practices. Thorpe was put on leave after a 24-year career and then pressured to leave, and Hamrick was fired. Shortly afterwards Thorpe and Hamrick bought the case they were joined by two other sales rep whistle-blowers. Then, in January 2011, the federal government in the US finally joined the case.

All four whistle-blowers will receive a-yet-to-be-decided portion of the $3 billion.

## ANTIDEPRESSANT USE IN NZ CHILDREN

In September 2011 the Green Party released figures they had obtained from Pharmac which revealed that the number of children and teenagers taking Prozac-style antidepressants, known as Selective Seretonin Re-uptake Inhibitors (SSRIs), had soared to almost 11,000 despite medical safety warnings. The Green Party wanted Medsafe to put warning labels on these drugs so patients and their families would know about the risks. Medsafe refused, saying the warnings were on its website and it had no plans to implement changes to have the warning labels on drug packets. This despite the fact that European countries required warning labels on such drugs and the FDA in the US required a black box warning which is the most serious label available for a prescription medicine.

In New Zealand the prescription of SSRIs to under 18-year-olds has increased by 31% in the four years from 2006 to 2010. In 2010 1855 prescriptions were written for children under the age of 13, a 20% increase from 2006. Most of these prescriptions were for Prozac which is subsidised by Pharmac through a generic brand named Fluox. In 2010 there were 13,792 prescriptions for all types of anti-depressants in those under 18.

As SSRIs are not approved for the treatment of depression in children and adolescents, patients or their parents must give consent to using the drug.


- Andrew Laxon. "Alarm at soaring use of happy pills." *NZ Herald*. 3 Sept 2011.

# AUGUST 5th CEREMONY

Sunday August 5th 2012 marked the 24th anniversary of the release of the Cartwright Report on the Inquiry into the treatment of cervical cancer at National Women's Hospital.

On that Sunday members of the Auckland Women's Health Council made their annual pilgrimage to the Spirit of Peace statue which still graces the entrance of the former National Women's Hospital. The statue has become a symbol of "the unfortunate experiment" and on August 5th each year AWHC members gather there to remember both the women who died as a result of the "unfortunate experiment" at the hospital as well as the women of Gisborne who died when the cervical screening programme that was established in the wake of the Cartwright Inquiry failed them. This year we were joined by Julie, the new director of Women's Health Action.

Since 1994 the ceremonial pilgrimage to the statue has been followed by a visit to the pohutukawa tree at the back of the former hospital. In September 1993 a plaque was unveiled beside a newly planted tree in memory of Dr Bill McIndoe, and Dr Malcolm McLean. Dr McIndoe was the cytologist and colposcopist at National Women's Hospital from 1963 -1983, and Dr McLean was the pathologist from 1961 - 1988. The tree was planted outside the clinic where the doctors used to work.

**What the ceremony represents**

For many of us the ceremony at the statue serves a number of purposes. It is a reminder of what happened in an era when the medical profession were able to experiment and practice on the bodies of women with seeming impunity, when whistle-blowers were nearly always effectively silenced, and some women died needlessly without ever knowing they had been part of a research trial into the development of cervical cancer. It also provides us with the opportunity to dedicate ourselves anew to the wide range of work all of us are involved in on women's health issues. Remembering the events of the past and the cost to those who tried to stop the "unfortunate experiment" enables us to see the current battles more clearly and to find the energy and enthusiasm to continue.

Unfortunately, there are still health professionals who refuse to accept the findings of the Inquiry or the recommendations contained in the Cartwright Report as was demonstrated recently during the National Women's Annual Clinical Report day held on 8 August. It is disturbing that 25 years after the Inquiry began, some obstetricians at Auckland City Hospital are using this event to continue to argue that Judge Silvia Cartwright got it wrong, there was no experiment, and Herbert Green was carefully monitoring the women in his care, women who slowly developed cervical cancer because they were not given the treatment they needed.

## *Children, Citizenship and Environment*

At the end of July the Child Poverty Action Group held their AGM which was followed by the launch of Bronwyn Hayward's book "*Children, Citizenship and Environment*." Bronwyn spoke about her work and the project that led to the writing of her book and she was joined by Rod Oram in a stimulating conversation on some of the issues in her book.

*"Children, Citizenship and Environment: Nurturing a democratic imagination in a changing world"* is an inspirational book that presents a new agenda for citizenship and environmental education which reflects the responsibility and opportunities facing teachers, parents and communities to support young citizens as they learn to 'make a difference' on the issues that concern them. The author, a senior lecturer in Political Science at the University of Canterbury, draws on lessons from New Zealand, a country where children often express a strong sense of personal responsibility for their planet but where many children face shocking social conditions.

The children of Christchurch were interviewed prior to the first of the devastating series of earthquakes which first struck Christchurch in September 2010. Half the author's royalties will be donated to child poverty projects following the earthquakes.

## AWHC GENERAL MEETING 19 July 2012

Detailed minutes of this meeting are available on request. Matters discussed included:

- Financial reports
- Grant applications
- ECART meetings
- Cervical screening committee
- Antenatal HIV screening
- Bioethics conference

Further information on some of the topics listed above is contained in this issue of the AWHC newsletter.

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# UP AND COMING EVENTS

## DISTRICT HEALTH BOARD meetings for August/September 2012:

**Waitemata DHB (Website address: www.waitematadhb.govt.nz)**
Some of the Waitemata and Auckland DHB meetings have moved to a 6-weekly meeting cycle.

The **combined Waitemata DHB and Auckland DHB** Community & Public Health Advisory Committee meeting starts at 2pm on Wednesday 29 August 2012.

Waitemata Hospital Advisory Committee meeting starts at 11am on Wednesday 19 September 2012 and will be followed by the DHB Full Board meeting which starts at 1.30pm. Both meetings will be held in the DHB Boardroom, Level 1, 15 Shea Terrace, Takapuna.

**Auckland DHB (Website address: www.adhb.govt.nz)**
The Hospital Advisory Committee meeting will be held at 9.30am on Wednesday 12 September 2012 followed by the Full Board meeting at 2pm. Both meetings will be held in the A+ Room, Clinical Education Centre, Auckland City Hospital.

**Counties Manukau DHB (Website address: www.cmdhb.org.nz)**
The Hospital Advisory Committee meeting will be held at 9am on Tuesday 28 August 2012 and will be followed by the Community & Public Health Advisory Committee meeting at 12.30pm at the Board Room at 19 Lambie Drive, Manukau City.

The Counties Manukau DHB Full Board meeting will be held at 1pm on Wednesday 5 September 2012 at 19 Lambie Drive, Manukau City.

## A SEMINAR ON CLINICAL ETHICS:

The Clinical Ethics Advisory Group of Waitemata DHB is holding a seminar, ***Resource Use in a Recession*** on Friday 21 September 2012 at the Awhina Conference Centre, Waitakere Hospital, Lincoln Road, Henderson, Auckland.

Speakers include Anthony Hill, Health & Disability Commissioner, Brandt Shortland, Northland Coroner, Professor David Richmond, geriatrician, Dr Barry Snow, neurologist, Dr Ian Dittmer, renal physician, Dr Martin Wilkinson, and Dr Jocelyn Benatar.

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